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10/057,561	01/29/2002	Johnson Chung	A8275	4657

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EXAMINER

LILLING, HERBERT J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,561

Applicant(s)

CHUNG ET AL.

Examiner

HERBERT J LILLING

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 11-15, 21-24 and 30-41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 1,6-10,16-20, 25-29 and 42-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-4,11-15, 21-24 and 30-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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1. Receipt is acknowledged of the response filed January 29, 2003.
2. Claims 1-4 and new claims 5-49 are now pending in this application.
3. Claims 1, 5, 6-10, 16-20, 25-29 and 42-49 are drawn to the elected invention.

Claims 2-4, 11-15, 21-24, and 30-41 have been withdrawn from consideration as directed to the non-elected invention.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claim 1, 6-10, 16-20, 25-29 and 42-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as **to enable** one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with respect to the microorganism per se, see the following:

It is apparent that specific mutant strain(s) is (are) required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of reasonable number of the mutant strain(s). See 37 C. F. R. 1.802.

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The specification does not provide a repeatable method for obtaining the strain and it does not appear to be a readily available material. Deposit of a strain would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably** removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification for the broad claimed language to support additional strains other than the deposited strain with specific identifying

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information commensurate in scope with the broad claims which includes morphology, physical and chemical properties.

Thus, Applicant has deposited only one strain, which has been allowed based on the instant specification but the specification is not enabling to support the **claims commensurate in scope with the written enabling description.**

B. Claims 1, 6-10, 16-20, 25-29 and 42-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for deposited strain as noted by claim 5, does not reasonably provide enablement for the exceptionally broad claimed terminology. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims absent any additional deposits or supporting evidence pertaining to guidance as to the distinguishing characteristics for the claimed subject matter. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of a reasonable number of the specific mutant strains.

C. The **written description requirement** for the claimed inventions have not been met by the instant specification absent a sufficient description of a representative number of species by the disclosure of relevant identifying characteristics which also includes the functional characteristics as claimed coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant application, the specification does not sufficiently describe a

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representative number of species by actual reduction to practice with their identifying characteristics.

Applicant has claimed microorganisms based on function only, without any disclosed or known correlation between the elements and their functions as demonstrated by their common identifying intrinsic properties. The prior art does not provide sufficient information on the subject to overcome the above deficiencies as to the intrinsic properties missing from the instant application to allow one of ordinary skill in the art to practice the instant inventions without having sufficient knowledge to know the scope of the properties of the mutant strains.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of microorganisms that can be mutated to the claimed functional language.

The specification deposited strain has been found to be enabling in view of the specification however, the specific mutated strain does not enable one to make and use additional strains as well as meet the requirements for deposits for any other strains in accordance with the rules of deposits thus **rendering the enablement as well as the written description of the instant specification defective as not meeting the requirements of the first paragraph of 35 U.S.C. 112.**

The specification lacks adequate written description for the claimed inventions for the formation of these additional mutagens in accordance with the written description requirements of 35 U.S.C. 112.

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures,

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diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the **enhanced bacterial strains** requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. Applicant's present no teachings on the metabolic pathways, gene mutations or sufficient information for formations of the additional (mutant, mutagen) strains commensurate in scope with the claimed language.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, that is the enhanced strain(s) is not a description of that material by claiming the strains by functional language as a comparison to a parental strain is not sufficient.

Thus, Claims 1, 6-10, 16-20, 25-29 and 42-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by **complete structure for the (mutagen) strain(s) or identifying characteristics which produce the strain(s)**, thus the description requirement has not been satisfied.

The test of enablement is whether one skilled in the art could make and use the claimed inventions from the disclosures in the specification coupled with the information known in the prior art without undue experimentation [*United States v. Teletronics*, 8 USPQ2d 1217 (Fed Cir. 1988)]. Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman* 230 USPQ 546 (Bd. Pat. & Inter 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) which includes these factors:

- 1) the **nature of the invention**-as indicated above the inventions are drawn to unknown intrinsic properties of broad species of strain(s) having functional language. The scope of the claimed broad enhanced bacterial strain(s) encompasses any microorganism having functional language which mutants identifying properties have not been described in the specification

- 2) the **state of the prior art** as drawn to mutant strains encompasses metabolic engineering pathways of all microorganisms is very unpredictable. The prior art does not teach such a vast amount of information so that the artisan, seeking to prepare and isolate any microorganism having the specified properties as it would be impossible to predictably engineer every microorganism to obtain the functional language absent any correlation and knowledge of the metabolic pathways of the microorganisms.

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3) the predictability or lack thereof in the art, There is no prior art for the predictability of the strain microorganisms metabolic pathways to form the claimed functional language.

4) the amount of direction or guidance present, Applicant has not presented a sufficient number of microorganisms for each species as well as for each type of (mutagen) strains. The examples are drawn to only one single MNNG mutant strain, which is not commensurate in scope with the claimed broad enhanced "Actinosynnema pretiosum", or "**enhanced bacterial**" strains. The example is drawn to one single process and there is no guidance as to process conditions for other strains to make and practice the instant inventions.

5) the presence or absence of working examples. Only one single mutant working example is not indicative of an ability to predictably practice the invention to modify the metabolic pathway with regard to all mutant microorganisms.

Unpredictability of the art

The art is highly unpredictable, as the metabolic engineering of one microorganism does not equate to an ability to perform such modification in another microorganism, which depends upon mechanisms of gene regulation and metabolite flow. Unless these pathways are known in each microorganism, the skilled artisan cannot make or use the invention commensurate with the scope of the claims without undue and unpredictable trial and error experimentation. **The amount of experimentation is undue and unpredictable because the skilled artisan would not know whether or not there was a reasonable expectation of success in modifying any microorganism by mutation to change the metabolic pathway to obtain the specified functional properties.** Thus, the Claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed specific deposited mutant microorganism as submitted in the example but does not reasonably provide enablement for commensurate in scope with the broad claimed microorganisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Hasegawa et al U.S. 4,331,598 for ATCC 31565 or Hasegawa et al U.S. 4,450,234 for ATCC 15005.

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Both of the deposited strains are considered to be within the scope of the broad claimed terminology since they have the same biological characteristics as claimed for the bacterium.

6. **Claim 6 is allowed.**

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is (703) 308-2034** and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit **1651**
August 11, 2003


Dr. Herbert J. Lilling
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Group 1600 Art Unit 1651